




Supplement for form 1449A/PTO (Modified) INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Complete if Known			
		Application Number	10772,768		
		Filing Date	February 4, 2004		
		First Named Inventor	David A. HORWITZ		
		Art Unit	1644		
		Examiner Name	Not Yet Assigned SANTO JALLA		
Sheet	1	of	9	Attorney Docket Number	A-68983-2

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	U.S. Patent Document Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
✓	A1	US 6,228,359 B1	05-08-2001	Horwitz	
	A2	US 6,358,506 B1	03-19-2002	Horwitz	
	A3	US 6,406,696 B1	06-18-2002	Bluestone	
	A4	US 6,447,765 B1	09-10-2002	Horwitz	
	A5 *	US 6,797,267 B2	09-28-2004	Horwitz	
	A6 *	US 6,803,036 B1	10-12-2004	Horwitz	
	A7 *	US 6,759,035 B2	07-06-2004	Horwitz	
	A8 *	US 2003/0012791 A1	01-16-2003	Horwitz	
	A9 *	US 2003/0039650 A1	02-27-2003	Gruenberg	
	A10 *	US 2003/0157057 A1	08-21-2003	Horwitz	
✓	A11 *	US 2004/0071667 A1	04-15-2004	Horwitz	

FOREIGN PATENT DOCUMENTS						
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✓	B1	WO 93/17698 A1	09-16-1993	Schering Corporation		
✓	B2	WO 97/42324 A1	11-13-1997	Schering Corporation		
✓	B3	WO 99/25366 A1	05-27-1999	University of Southern California		
✓	B4	WO 99/48524 A1	09-30-1999	University of Southern California		
✓	B5 *	WO 00/00587 A1	01-06-2000	Kaltoft et al.		
✓	B6	WO 00/66158 A2	11-09-2000	University of Southern California		
✓	B7	WO 01/16296 A2	03-08-2001	University of Southern California		
✓	B8 *	WO 01/77299 A2, A3	10-18-2001	University of Southern California		
✓	B9 *	WO 2003/059264 A3	07-24-2003	University of Southern California		

NON PATENT LITERATURE DOCUMENTS					
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	C1	ANASETTI et al., "Treatment of acute graft-versus-host disease with a nonmitogenic anti-CD3 monoclonal antibody", Transplantation 54:844-851 (1992).			

Examiner Signature		Date Considered	2/9/06
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<input checked="" type="checkbox"/>	C2	ASAI O, et al., "Suppression of graft-versus-host disease and amplification of graft-versus-tumor effects by activated natural killer cells after allogeneic bone marrow transplantation," <i>Journal of Clinical Investigation</i> 101(9):1835-1842 (1998).		
<input checked="" type="checkbox"/>	C3	ASANO M, et al., "Autoimmune disease as a consequence of developmental abnormality of a T cell subpopulation." <i>J Exp Med.</i> , 184(2):387-96 (1996 Aug 1).		
<input checked="" type="checkbox"/>	C4	AUCHINCLOSS, Hugh Jr., et al, in <i>Fundamental Immunology</i> 4th Ed., Paul, W.E. (ed.) Lippincot-Raven: Philadelphia, New York; 1999 pp. 1182-1222.		
<input checked="" type="checkbox"/>	C5	BARKER et al., "Identification of multiple and distinct CD8+ T cell suppressor activities: dichotomy between infected and uninfected individuals, evolution with progression of disease, and sensitivity to gamma irradiation," <i>J Immunol</i> 156:4476-4483 (1996).		
<input checked="" type="checkbox"/>	C6	BETZ, M. and FOX, B.S., "Prostaglandin E2 inhibits production of Th1 lymphokines but not of Th2 lymphokines," <i>J Immunol.</i> , 146(1):108-13 (1991 Jan 1).		
<input checked="" type="checkbox"/>	C7	BLAZAR et al., "Both CD4+ and CD8+ T Cells Can Cause Accelerated GVHD Lethality in the Presence of High In Vivo Doses of Exogenous IL10: Role of Interferon Gamma (IFNγ) in GVHD Induction, <i>Blood</i>, 88:247 (1996) (abstract)		
<input checked="" type="checkbox"/>	C8	BLAZAR et al., "FK506 inhibits graft-versus-host disease and bone marrow graft rejection in murine recipients of MHC disparate donor grafts by interfering with mature peripheral T cell expansion post-transplantation", <i>J. Immunol</i> 153:1836-1846 (1994).		
<input checked="" type="checkbox"/>	C9	BLAZAR et al., "Murine recipients of fully mismatched donor marrow are protected from lethal graft-versus-host disease by the in vivo administration of rapamycin but develop an autoimmune-like syndrome", <i>J. Immunol</i> 151:5726-5741 (1993).		
<input checked="" type="checkbox"/>	C10	BLAZAR et al., "Recent advances in graft-versus-host disease (GVHD)", <i>Immunol Rev</i> 157:79-90 (1997).		
<input checked="" type="checkbox"/>	C11	BONIG et al., "Transforming Growth Factor- β Suppresses Interleukin-15-Mediated Interferon- γ Production in Human T Lymphocytes," <i>Scand. J Immunol.</i> , 50:612-618 (December 1999).		
<input checked="" type="checkbox"/>	C12	BONINI et al., "HSY-TK gene transfer into donor lymphocytes for control of allogeneic graft-versus-leukemia, <i>Science</i> 276:1719-1724 (1997).		
<input checked="" type="checkbox"/>	C13	BORDER et al., "Transforming growth factor-beta in disease: the dark side of tissue repair," <i>J Clin Invest</i> 90:1-7 (1992)		
<input checked="" type="checkbox"/>	C14	BOUSSIOTIS et al., "B7 but not intercellular adhesion molecule-1 costimulation prevents the induction of human alloantigen-specific tolerance," <i>J Exp Med</i> 178:1753-1763 (1993).		
<input checked="" type="checkbox"/>	C15	BOUSSIOTIS, "Altered T-cell receptor + CD28-mediated signaling and blocked cell cycle progression in interleukin 10 and transforming growth factor- β -treated alloreactive T cells that do not induce graft-versus-host disease," <i>Blood</i> , 97:565-571 (Jan 2001).		
<input checked="" type="checkbox"/>	C16	BUGY, R.P. et al., <i>FASEB J.</i> 1995 9:A497 (Abstract).		
<input checked="" type="checkbox"/>	C17	CHANDRASEKAR, B., et al., "Dietary calorie restriction inhibits transforming growth factor-beta (TGF- β) expression in murine lupus nephritis", 9th International Congress on Immunology, 848 (1995).		
<input checked="" type="checkbox"/>	C18	CHAVIN et al., "Anti-CD2 mAbs Suppress Cytotoxic Lymphocyte Activity by the Generation of Th2 Suppressor Cells and Receptor Blockade," <i>J Immunol</i> 152:3729-3739 (1994).		

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Examiner Signature	<i>Sanjoo</i>	Date Considered	2/9/06
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✓	C19	CHEN et al., "T Cells Specific for a Polymorphic Segment of CD45 Induce Graft-Versus-Host Disease with Predominant Pulmonary Vasculitis," J. Immunology, 161:909-918 (1998).	
✓	C20	CHONG P. et al. "Inhibition of protein-kinase C in peripheral blood mononuclear cells of patients with systemic lupus erythematosus: effect on spontaneous immunoglobulin production," Autoimmunity, 10:227-231 (1991).	
✓	C21	COSIMI, A.B., et al., "Treatment of acute renal allograft rejection with OKT3 monoclonal antibody," Transplantation, 32(6):535-9 (1981 Dec).	
✓	C22	DEL ROSARIO et al., "Prevention of Graft-Versus-Host Disease by Induction of Immune Tolerance With Ultraviolet B-Irradiated Leukocytes in H-2 Disparate Bone Marrow Donor," Blood, 93(10):3558-3564 (May 1999).	
✓	C23	DELGIUDICE, G., et al., "TGF-beta activity is increased in systemic lupus erythematosus (SLE) and progressive systemic sclerosis (PSS)," Arthritis and Rheumatism Vol. 36 (9 Suppl.) p S196(Sept. 1993).	
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✓	C25	DUMONT et al., "Distinct Mechanisms of Suppression of Murine T Cell Activation by the Related macrolides FK-506 and Rapamycin", J. Immunol 144:251-258 (1990).	
✓	C26	DUPONT, B., "Immunology of hematopoietic stem cell transplantation: a brief review of its history", Immunol Reviews 157:5-12 (1997).	
✓	C27	EARLY et al., "Rapid conversion of naïve to effector T cell function counteracts diminished primary human newborn T cell responses," Clin Exp Immunol, 1163:L527-533, abstract (June 1999).	
✓	C28	FAST, "Generation and characterization of IL-2-activated veto cells", J Immunol 149:1510-1515 (1992).	
✓	C29	FERNANDES, G., et al., "Calorie restriction delays autoimmune murine lupus by differentially modulating oncogenes and TGF- beta-1 expression", 9th International Congress on Immunology., 848 (1995).	
✓	C30	FOWLER et al., "Donor CD4-enriched cells of Th2 cytokine phenotype regulate graft-versus-host disease without impairing allogeneic engraftment in sublethally irradiated mice", Blood 84:3540-3549 (1994).	
✓	C31	GAO Q, et al., "CD4+CD25+ cells regulate CD8 cell anergy in neonatal tolerant mice." Transplantation, 68(12):1891-7 (1999 Dec 27).	
✓	C32	GARDERET et al., "Effective depletion of alloreactive lymphocytes from peripheral blood mononuclear cell preparations," Transplantation, 67(1):124-130 (January 1999).	
✓	C33	GOLDMAN et al., "Bone marrow transplantation for chronic myelogenous leukemia in chronic phase. Increased risk for relapse associated with T-cell depletion", Ann Intern Med 108:806-814 (1988).	
✓	C34	GRATAMA et al., "Treatment of Acute Graft-Versus-Host Disease With Monoclonal Antibody OKT3. Clinical results and effect on circulating T lymphocytes", Transplantation 38(5):469-474 (1984).	
	C35	GRAY et al., "Activated Natural Killer Cells Can Induce Resting B Cells to Produce Immunoglobulin," Arthritis & Rheumatism, 37(9)suppl:S278 (1994).	Source missing
✓	C36	GRAY et al., "Generation of an Inhibitory Circuit Involving CD8+ T Cells, IL-2 and NK Cell-Derived TGF-β: Contrasting Effects of Anti-CD2 and Anti-CD3", J Immunol, 160:2248-2254 (1998).	
✓	C37	GRAY et al., "The Role of Transforming Growth Factor β in the Generation of Suppression: an Interaction Between CD8+ T and NK Cells," J Exp Med 180:1937-1942 (1994).	

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✓	C38	GRIBBEN et al., "Complete blockade of B7 family-mediated costimulation is necessary to induce human alloantigen-specific anergy: a method to ameliorate graft-versus-host disease and extend the donor pool", <i>Blood</i> 97:4887-4893 (1996).	
	C39	GROUX, H., et al., "A CD4+ T-cell subset inhibits antigen-specific T-cell responses and prevents colitis," <i>Nature</i> , 389(6652):737-42 (1997 Oct 16).	
	C40	HAHN, B.H., Dubois' Lupus Erythematosus, 5th Ed. (1997), pp. 69-76 (D.J. Wallace et al. eds., Williams and Wilkins, Baltimore).	
	C41	HALVERSON et al., "In Vitro Generation of Allospecific Human CD8+ T Cells of Tc1 and Tc2 Phenotype," <i>Blood</i> , 90(5):2089-2096 (September 1997).	
	C42	HAN, et al., "A New Type of CD4+ Suppressor T cell Completely Prevents Spontaneous Autoimmune Diabetes and Recurrent Diabetes in Syngeneic Islet-Transplanted NOD Mice," <i>Journal of Autoimmunity</i> , 9:331-339 (1996).	
✓	C43	HEITGER et al., "Essential Role of the Thymus to Reconstitute Naïve (CD45RA+) T-Helper Cells After Human Allogeneic Bone Marrow Transplantation", <i>Blood</i> , 90(2):850-857 (July 1997).	
	C44	HERVE et al., "Treatment of Corticosteroid-Resistant Acute Graft-Versus-Host Disease by In Vivo Administration of Anti-Interleukin-2 Receptor Monoclonal Antibody (B-B10)", <i>Blood</i> 75(4):1017-1023 (1990). —	Author misidentified
✓	C45	HIROHATA et al., "Role of IL-2 in the generation of CD4+ suppressors of human B cell responsiveness", <i>J Immunol.</i> , 142:3104-3112 (1989)	
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	C52	JACKSON AL, et al., "Restricted expression of p55 interleukin 2 receptor (CD25) on normal T cells." <i>Clin Immunol Immunopathol.</i> , 54(1):126-33 (1990 Jan).	
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Q	C55	KINTER et al., "Interleukin 2 induces CD8+ T cell-mediated suppression of human immunodeficiency virus replication in CD4+ T cells and this effect overrides its ability to simulate virus expression", <i>Proc. Natl. Acad. Sci. USA</i> 92:10985-10989 (1995).	
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	C62	LANCASTER, F., et al., "Anti-idiotypic T cells suppress rejection of renal allografts in rats," <i>Nature.</i> , 1985 May 23-29;315(6017):336-7.	
	C63	LANGREHR, J.M., et al., "Evidence that nitric oxide production by in vivo allosensitized cells inhibits the development of allospecific CTL," <i>Transplantation</i> , 53(3):632-40 (1992 Mar).	
	C64	LARSEN, C.P., et al., "Long-term acceptance of skin and cardiac allografts after blocking CD40 and CD28 pathways," <i>Nature</i> , 381(6581):434-8 (1996 May 30).	
	C65	LINKER-ISRAELI M, et al., "CD8+ lymphocytes from patients with systemic lupus erythematosus sustain, rather than suppress, spontaneous polyclonal IgG production and synergize with CD4+ cells to support autoantibody synthesis," <i>Arthritis Rheum.</i> , 33(8):1216-25 (1990 Aug).	
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	C68	MARTIN et al., "Effects of treating marrow with a CD3-specific immunotoxin for prevention of acute graft-versus-host disease", <i>Bone Marrow Transplant</i> 3:437-444 (1989).	
	C69	MARTIN, "Overview of Marrow Transplantation Immunology", in <i>Bone Marrow Transplantation</i> (eds. Forman et al.) pp. 16-21, Boston, Blackwell Scientific Publications (1994).	
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	C71	MASSAGUE J., "The transforming growth factor-beta family," <i>Annu Rev Cell Biol.</i> , 6:597-641 (1990).	
Q	C72	MASSAGUE, "Receptors for the TGF-beta family", <i>Cell</i> 69:1067-1070 (1992).	

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			Application Number	10/772,768	
			Filing Date	February 4, 2004	
			First Named Inventor	David A. HORWITZ	
			Art Unit	1644	
			Examiner Name	Not Yet Assigned SANJOO JALLA	
Sheet	6	of	9	Attorney Docket Number	A-68983-2

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✓	C73	MIZUOCHI, T., et al., "Both L3T4+ and Lyt-2+ helper T cells initiate cytotoxic T lymphocyte responses against allogeneic major histocompatibility antigens but not against trinitrophenyl-modified self," <i>J Exp Med.</i> , 62(2):427-43 (1985 Aug 1).	
✓	C74	MORRIS, "Prevention and treatment of allograft rejection in vivo by rapamycin: molecular and cellular mechanisms of action", <i>Ann NY Acad Sci</i> 685:68-72 (1993).	
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✓	C76	MYSLIWIEZ et al., "Antilymphocytic antibodies and marrow transplantation. XII. Suppression of graft-versus-host disease by T cell modulating and depleting antimuscle GD3 antibody is most effective when preinjected in the marrow recipient," <i>Blood</i>, 80(10):2661-2667, abstract (November 1992).	Ref. could not be located
✓	C77	OHTSUKA, K., et al., "Decreased Production of TGF- β by Lymphocytes from Patients with Systemic Lupus Erythematosus", <i>J. Immunol.</i> , 160:2539-2545 (1998).	
✓	C78	OSWALD, et al., "IL-10 Synergizes with IL-4 and Transforming Growth Factor-Beta to Inhibit Macrophage Cytotoxic Activity," <i>J Immunology</i> 148(11):3578-3582 (1992).	Ref. could not be located
✓	C79	PAPIERNIK M, et al., "T cell deletion induced by chronic infection with mouse mammary tumor virus spares a CD25-positive, IL-10-producing T cell population with infectious capacity." <i>J Immunol.</i> , 158(10):4642-53 (1997 May 15).	
✓	C80	PATTERSON et al., "Graft rejection following HLA matched T-lymphocyte depleted bone marrow transplantation", <i>Br J Haematol</i> 63:221-230 (1986).	
✓	C81	PAWELEC, et al., "Cytokine Modulation of TH1/TH2 Phenotype Differentiation in Directly Alloresponsive CD4+ Human T Cells," <i>Transplantation</i> , 62(8):1095-1101 (October 1996).	
✓	C82	PEARCE, N.W., et al., "Specific unresponsiveness in rats with prolonged cardiac allograft survival after treatment with cyclosporine. V. Dependence of CD4+ suppressor cells on the presence of alloantigen and cytokines, including interleukin 2," <i>Transplantation</i> , 55(2):374-80 (1993 Feb).	
✓	C83	PESCOVITZ, M.D., et al., "Effect of class II antigen matching on renal allograft survival in miniature swine," <i>J Exp Med.</i> , 160(5):1495-508 (1984 Nov 1).	
✓	C84	POWRIE F, et al., "A critical role for transforming growth factor-beta but not interleukin 4 in the suppression of T helper type 1-mediated colitis by CD45RB(low) CD4+ T cells." <i>J Exp Med.</i> , 183(6):2669-74 (1996 Jun 1).	
✓	C85	QIN, L., et al., "Gene transfer for transplantation. Prolongation of allograft survival with transforming growth factor-beta 1," <i>Ann Surg.</i> , 220(4):508-18; discussion 518-9 (1994 Oct).	
✓	C86	QIN, L., et al., "Retrovirus-mediated transfer of viral IL-10 gene prolongs murine cardiac allograft survival," <i>J Immunol.</i> , 156(6):2316-23 (1996 Mar 15).	
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✓	C89	READ S, et al., "Cytotoxic T lymphocyte-associated antigen 4 plays an essential role in the function of CD25(+)CD4(+) regulatory cells that control intestinal inflammation." <i>J Exp Med.</i> , 192(2):295-302 (2000 Jul 17).	

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
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			Application Number	10/772,768	
			Filing Date	February 4, 2004	
			First Named Inventor	David A. HORWITZ	
			Art Unit	1644	
			Examiner Name	Not Yet Assigned SANDO JALA	
Sheet	7	of	9	Attorney Docket Number	A-68983-2

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	C90	ROCHA, B., et al., "Clonal anergy blocks in vivo growth of mature T cells and can be reversed in the absence of antigen," <i>J Exp Med.</i> , 177(5):1517-21 (1993 May 1).	
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


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
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			First Named Inventor	David A. HORWITZ
			Art Unit	1644
			Examiner Name	Not Yet Assigned SANTOO JALIA
			Attorney Docket Number	A-68983-2
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	C111	TAKAHASHI T, et al., "Immunologic self-tolerance maintained by CD25+CD4+ naturally anergic and suppressive T cells: Induction of autoimmune disease by breaking their anergic/suppressive state." Int Immunol., 10(12):1969-80 (1998 Dec).	
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	C114	THORNTON AM and Shevach EM. "Suppressor effector function of CD4+CD25+ immunoregulatory T cells is antigen nonspecific." J Immunol., 164(1):183-90 (2000 Jan 1).	
	C115	TOMITA, Y., et al., "Importance of suppressor T cells in cyclophosphamide-induced tolerance to the non-H-2-encoded alloantigens. Is mixed chimerism really required in maintaining a skin allograft tolerance?" J Immunol., 144(2):463-73 (1990 Jan 15).	
	C116	VALLERA et al., "Bone marrow transplantation across major histocompatibility barriers in mice. Effect of elimination of T cells from donor grafts by treatment with monoclonal Thy-1.2 plus complement or antibody alone", Transplantation 31:218-222 (1981).	
	C117	VENDETTI, S., et al., "Anergic T cells inhibit the antigen-presenting function of dendritic cells," J Immunol., 165(3):1175-81(2000 Aug 1).	
	C118	VERBANAC, K.M., et al., "A role for transforming growth factor-beta in the veto mechanism in transplant tolerance," Transplantation, 57(6):893-900 (1994 Mar 27).	
	C119	VIA et al., "Critical Role of interleukin-2 in the development of acute graft-versus-host disease", International Immunol 5:565-572 (1993).	
	C120	WAHL SM. "Transforming growth factor beta: the good, the bad, and the ugly." J Exp Med., 180(5):1587-90 (1994 Nov 1).	
	C121	WEINER HL, et al., "Oral tolerance: immunologic mechanisms and treatment of animal and human organ-specific autoimmune diseases by oral administration of autoantigens." Annu Rev Immunol., 12:809-37 (1994).	
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<input checked="" type="checkbox"/>	C123	WILSON, D.B., "Idiotypic regulation of T cells in graft-versus-host disease and autoimmunity," <i>Immunol Rev.</i> , 107:159-77 (1989 Feb).	
<input checked="" type="checkbox"/>	C124	ZEHAVI-WILLNER et al., "The Mitogenic Activity of Staphylococcal Enterotoxin B (SEB): A Monovalent T Cell Mitogen That Stimulates Cytolytic T Lymphocytes but Cannot Mediate Their Lytic Interaction," <i>Journal of Immunology</i> 127(8):2682-2687 (1986).	
<input checked="" type="checkbox"/>	C125	ZELLER et al., "Induction of CD4+ T Cell Alloantigen-Specific Hyporesponsiveness by IL-10 and TGF- β ¹ , <i>Journal of Immunology</i> 163:3684-3691 (1999).	
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<input checked="" type="checkbox"/>	C127	ZHENG, X.X., et al., "Administration of noncytolytic IL-10/Fc in murine models of lipopolysaccharide-induced septic shock and allogeneic islet transplantation," <i>J Immunol</i> , 154(10):5590-600 (1995 May 15).	

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